

NOT FOR PUBLICATION

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

MIRRIAM PIERRE,

Plaintiff,

v.

OTSUKA AMERICA
PHARMACEUTICALS,

Defendant.

Civil Action No. 23-21848 (MAS) (DEA)

MEMORANDUM OPINION

This matter concerns alleged retaliation in violation of the New Jersey Conscientious Employee Protection Act (the “CEPA”), N.J. Stat. Ann. § 34:19-1 *et seq.* Currently before the Court are two motions: one by Defendant Otsuka American Pharmaceutical Development & Commercialization Inc. (“Otsuka” or “Defendant”)¹ to dismiss Plaintiff’s Amended Complaint under Federal Rule of Civil Procedure² 12(b)(6) (ECF No. 20), and one by Plaintiff Mirriam Pierre (“Plaintiff”) to remand this case to the Superior Court of New Jersey, Somerset County (ECF No. 7). The Court has considered the parties’ moving, opposition, and reply papers, and decides the matter without oral argument pursuant to Local Civil Rule 78.1. For the reasons stated below, Plaintiff’s Motion to Remand is denied. Defendant’s Motion to Dismiss is granted.

¹ Defendant states that it has been improperly named in the Complaint as “Otsuka America Pharmaceuticals.” (Def.’s Opp’n Br. 1, ECF No. 9.) Neither party has moved to amend the caption to date.

² Unless otherwise noted, all references to “Rule” or “Rules” hereinafter refer to the Federal Rules of Civil Procedure.

I. BACKGROUND

A. Factual Background

The following facts are derived from the Amended Complaint.³ (Am. Compl., ECF No. 17.) Plaintiff was employed with Otsuka as a Senior Director and Head of Data Management from December 2020 until January 2023. (*Id.* ¶¶ 6-7.) Otsuka is a pharmaceutical company that develops health products and pharmaceutical drugs to treat various diseases and health conditions. (*Id.* ¶¶ 18-19.)

While employed with Otsuka, Plaintiff was assigned to a group responsible for handling data of pre-market drugs to ensure the integrity of Otsuka's database in preparation for clinical trials. (*Id.* ¶¶ 20-22.) Specifically, Plaintiff's group "collected, cleaned[,] and locked data" for all of Otsuka's clinical trials from December 2020 to January 2023. (*Id.* ¶ 20.) At the start of Plaintiff's employment, her group was comprised of 15 members and tasked with handling 14 clinical trials. (*Id.* ¶ 26.) By January 2023, Plaintiff was responsible for 37 clinical trials, but her group dwindled to 9 members. (*Id.* ¶ 27.) This reduction in headcount is alleged to have "affected the quality of data being collected, cleaned[,] and locked." (*Id.* ¶ 28.)

Beginning in the summer of 2022, Plaintiff made monthly presentations to Otsuka's Research and Development Team ("RDLT") to address certain issues that were affecting the group. (*Id.* ¶¶ 9-15.) These issues included, among other things: (1) "Otsuka's decision to refuse approval for [an] adequate headcount" which compromised "[Plaintiff's] department's ability to ensure data integrity"; (2) "Otsuka's database lock period was unreasonably short and objectively shorter than industry standard"; (3) Otsuka's "site lock process" jeopardized "patient safety and

³ The Court, as it must, accepts as true all of Plaintiff's well-pleaded factual allegations and "construe[s] the complaint in the light most favorable to [P]laintiff." *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009) (citation omitted).

data integrity”; and (4) Otsuka’s failure to disclose adverse events risked presenting misleading data to regulatory authorities such as the Food and Drug Administration (“FDA”). (*Id.* ¶¶ 10-15.)

Plaintiff states that, as these issues surfaced, members of the RDLT became “increasingly upset” and Plaintiff was “aggressively questioned” on the information she was presenting during the RDLT meetings. (*Id.* ¶¶ 81-82.) Plaintiff alleges that she was asked by two individuals outside of the RDLT “not to continue to raise these issues.” (*Id.* ¶ 83.) Based on Plaintiff’s ongoing concerns regarding the “implications on patient health and safety that could arise from improperly cleaned and locked data[,]” Plaintiff “continued to raise these concerns” with the RDLT—all of which went unanswered. (*Id.* ¶¶ 89, 91-92.) According to Plaintiff, this caused Otsuka’s leadership team to become “increasingly hostile and aggressive towards [Plaintiff] with the hopes that they could push her to quit her job.” (*Id.* ¶ 93.)

Specifically, it is alleged that two members of the leadership team, Carol Augustine (“Augustine”) and Debbie Profit (“Profit”) retaliated against Plaintiff by engaging in conduct that included, but was not limited to: stating that Plaintiff was “not capable of performing the role of [Senior] Director[,]” isolating Plaintiff from her peers by stating she was a “‘bad’ employee”, creating a culture which excluded those who objected to the status quo, making disparaging comments about Plaintiff, and “repeatedly humiliat[ing] Plaintiff in meetings by minimizing the evidence [Plaintiff] provided on the data issues found.” (*Id.* ¶¶ 83, 110-23.) Because Plaintiff’s group remained “understaffed” and in light of ongoing concerns over the “risky professional position that Otsuka had put her in,” Plaintiff states that she had no option but to resign from her position with Otsuka in January 2023. (*Id.* ¶ 94.)

B. Procedural History

Several months after Plaintiff's resignation, in October 2023, this action was filed in the Superior Court of New Jersey, Somerset County ("State Court") alleging a single claim against Defendant under the CEPA. (*See* State Court Complaint, annexed to Notice of Removal, Ex. A, ECF No. 1-1.) Defendant timely removed this action in November 2023.⁴ (*See* Notice of Removal, ECF No. 1.) The instant motions followed.

II. LEGAL STANDARD

A. Remand

A motion to remand is governed by 28 U.S.C. § 1447(c), which provides that a case removed to federal court shall be remanded "[i]f at any time before final judgment it appears that the district court lacks subject matter jurisdiction." After a matter is filed in state court, a defendant may remove any action over which the federal courts have jurisdiction. 28 U.S.C. § 1441(a). The party removing the action has the burden of establishing federal jurisdiction. *Steel Valley Auth. v. Union Switch & Signal Div.*, 809 F.2d 1006, 1010 (3d Cir. 1987). Removal statutes are "strictly construed against removal and all doubts should be resolved in favor of remand." *Id.* For removal to be proper, a federal court must have original jurisdiction; that is, the removed claims must arise from a "right or immunity created by the Constitution or laws of the United States[.]" or there must be complete diversity between the parties. *Concepcion v. CFG Health Sys. LLC*, No. 13-2081, 2013 WL 5952042, at *2 (D.N.J. Nov. 6, 2013); *see also* 28 U.S.C. § 1332.

To satisfy the jurisdictional requirements of 28 U.S.C. § 1332(a)(1), the federal diversity statute, no plaintiff can be a citizen of the same state as any of the defendants and the amount in

⁴ Plaintiff's Amended Complaint followed the Notice of Removal and was filed on December 15, 2023. (*See* Am. Compl.)

controversy must exceed \$75,000.00. *Carden v. Arkoma Assocs.*, 494 U.S. 185, 187 (1990); *Schneller ex rel. Schneller v. Crozer Chester Med. Ctr.*, 387 F. App'x 289, 292 (3d Cir. 2010). For purposes of diversity jurisdiction, “a corporation shall be deemed to be a citizen of every State and foreign state by which it has been incorporated and of the State or foreign state where it has its principal place of business[.]” 28 U.S.C. § 1332(c)(1).

B. Rule 12(b)(6)

Federal Rule of Civil Procedure 12(b)(6) permits a motion to dismiss when a complaint fails “to state a claim upon which relief can be granted[.]” For a complaint to survive dismissal under Rule 12(b)(6), it must contain sufficient factual matter to “state a claim that is plausible on its face.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). A claim is facially plausible “when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Id.* Further, a plaintiff must “allege sufficient facts to raise a reasonable expectation that discovery will uncover proof of her claims.” *Connelly v. Lane Constr. Corp.*, 809 F.3d 780, 789 (3d Cir. 2016). In evaluating the sufficiency of a complaint, district courts must separate the factual and legal elements. *Fowler*, 578 F.3d at 210-11. Restatements of the elements of a claim are legal conclusions, and therefore, not entitled to a presumption of truth. *Burtch v. Milberg Factors, Inc.*, 662 F.3d 212, 224 (3d Cir. 2011). The Court, however, “must accept all of the complaint’s well-pleaded facts as true[.]” *Fowler*, 578 F.3d at 210. Even if plausibly pled, however, a complaint will not withstand a motion to dismiss if the facts alleged do not state “a legally cognizable cause of action.” *Turner v. J.P. Morgan Chase & Co.*, No. 14-7148, 2015 WL 12826480, at *2 (D.N.J. Jan. 23, 2015).

III. ANALYSIS

A. Plaintiff's Motion to Remand

i. *Parties' Arguments*

Defendant has removed this action based on diversity of citizenship, 28 U.S.C. §§ 1332 and 1441. (Notice of Removal ¶ 4.) While both parties maintain that Plaintiff is a citizen of New Jersey, the parties dispute Defendant's citizenship. (*Compare id.* ¶ 1, with Am. Compl. ¶ 2.) For establishing citizenship, Defendant claims that it is a citizen of Delaware and Maryland because it is incorporated in Delaware and has a principal place of business in Maryland. (Notice of Removal ¶ 6.) Plaintiff, on the other hand, claims that Defendant's principal place of business is in New Jersey, and thus complete diversity is lacking in this action, warranting remand. (*See generally* Am. Compl. ¶ 2; Pl.'s Mot. Remand, ECF No. 7.)

Plaintiff argues that Defendant's principal place of business is in New Jersey, as opposed to Maryland, given that its "nerve center" is in Princeton, New Jersey. (Pl.'s Mot. Remand *4⁵.) Specifically, Plaintiff claims that Defendant has a stronger connection to its New Jersey office than its Maryland office, given that: (1) Defendant's New Jersey office has four floors, while Defendant's Maryland office occupies only one and a half floors (*Id.* at *4, *8); (2) Defendant's website lists the New Jersey office first in its locations (*Id.*); (3) Defendant filed documents with the State of New Jersey listing that its officers are located at the New Jersey address (*Id.*); (4) Defendant's "research and development, the chief medical officer's team, the legal team, the human resources team, the safety team, and many other core corporate functions" are maintained in the New Jersey office (*Id.* at *5); and (5) Defendant indicated its location as Princeton, New

⁵ Page numbers preceded by an asterisk reflect page numbers atop the ECF header.

Jersey, in press releases. (*Id.* at *6, *9; *see also* Decl. of Mirriam Pierre [“Pierre Decl.”], Ex. E, annexed to Pl.’s Mot. Remand, ECF No. 7-7.)

Defendant responds that the Notice of Removal correctly identifies its principal place of business as Rockville, Maryland, because this is where Otsuka’s CEO and senior officers, including members of its Executive Leadership Team (“ELT”), direct, control, and coordinate the corporation’s activities. (Def.’s Opp’n Br. 2, 5.) In support, Defendant refers to a Declaration of its Vice President and General Counsel, Karen Gally (“Gally”), which is appended to the Notice of Removal and its opposition brief.⁶ (*See* Decl. of Karen Gally [“Gally Decl.”], annexed to Def.’s Opp’n Br., ECF No. 9-1; *see also* Notice of Removal, Ex. D.) Gally certifies that, since starting its business in Maryland in 2002, Defendant expanded its presence and currently has offices in New Jersey and California, “yet its original ‘home office’ and current principal place of business remains in Rockville, Maryland, from which the corporation is run.” (Def.’s Opp’n Br. 4 (citing Gally Decl. ¶¶ 4-5).) Further, Gally states that many of Defendant’s “high-level officers” work in the Maryland office, including herself and Kevin Henley (“Henley”), the Vice President and U.S. Chief Compliance Officer. (*Id.* ¶ 7 (citing Gally Decl. ¶ 14).)

Critically, Tarek Rabah (“Rabah”), Otsuka’s President and Chief Executive Officer (“CEO”), lives in Maryland and works out of the Maryland offices. (Gally Decl. ¶ 8.) In his capacity as President and CEO, Rabah exercises decision making authority over Defendant’s business affairs and employees, and high-level officers report directly to him. (*Id.* ¶¶ 9-10.) From the Maryland office, Rabah makes corporate decisions for Defendant, often based on the advice

⁶ “In evaluating the citizenship of corporate parties, district courts are permitted to rely upon the parties’ sworn affidavits setting forth their proper places of incorporation and principal place of business.” *Chang v. Bank of N.Y. Mellon Corp.*, No. 17-11061, 2018 WL 278737, at *2 (D.N.J. Jan. 2, 2018) (citation omitted).

and guidance of the ELT. (*Id.* ¶¶ 10-13.) Through his role as President, CEO, and Chair of the ELT, Rabah exercises day-to-day “decision-making authority” from the Maryland office, with the exclusion of travel to other offices and vacation. (*Id.* ¶ 10.) Accordingly, Defendant asserts that this Court should retain jurisdiction and deny Plaintiff’s Motion to Remand. (*See generally* Def.’s Opp’n Br.)

ii. Analysis

At the outset, the Court notes that there is no dispute among the parties that Plaintiff satisfies the amount in controversy requirement and that Plaintiff is a citizen of New Jersey. (*See generally* Pl.’s Mot. Remand.; *see also* Notice of Removal ¶ 1.) Solely at issue is whether Defendant’s principal place of business creates complete diversity allowing this Court to properly exercise diversity jurisdiction. *See* 28 U.S.C. § 1332 (requiring complete diversity of citizenship, *i.e.*, all plaintiffs are diverse from all defendants); *see also Johnson v. SmithKline Beecham Corp.*, 724 F.3d 337, 346 (3d Cir. 2013).

“For the purposes of [28 U.S.C. §§ 1332 and 1441], a corporation shall be deemed to be a citizen of every State . . . by which it has been incorporated and of the State . . . where it has its principal place of business.” 28 U.S.C. § 1332(c)(1). It is well settled that—under the Supreme Court’s precedent in *Hertz Corp. v. Friend*—a corporation’s principal place of business is its “nerve center.” 559 U.S. 77, 78 (2010). The nerve center is “where a corporation’s high-level officers direct, control, and coordinate the corporation’s activities.” *Id.* Even in cases where a company has multiple offices and its officers travel to different locations, a corporation can only have one principal place of business. *Sandoval v. LifeCell Corp.*, No. 21-17705, 2021 WL 6498110, at *2 (D.N.J. Dec. 3, 2021) (citing *Hertz*, 559 U.S. at 94-96).

In illustrating this point, the Supreme Court in *Hertz* explained that where a company's business activities are visible to the public to take place in state "Y", but its top officers in fact direct activities from a different state "X," then the principal place of business is state X because that is where the company is being controlled. 559 U.S. at 96. Indeed, the nerve center is "not simply an office where the corporation holds its board meetings (for example, attended by directors and officers who have traveled there for the occasion)." *Id.* at 93. *Hertz* also clarified that "mere filing[s] of a form like the Securities and Exchange Commission's Form 10-K listing a corporation's 'principal executive offices' would, without more, be sufficient proof to establish a corporation's 'nerve center.'" *Id.* at 97.

Based on *Hertz*'s longstanding precedent, the focal point for establishing a company's principal place of business is where the center of overall direction, control, and coordination occurs. 559 U.S. at 94-96. In making this determination, a "key consideration" is where the president and CEO reports to work. *Aizen v. Am. Healthcare Admin. Servs.*, No. 18-15195, 2019 WL 4686811, at *5 (D.N.J. Sept. 26, 2019) (citing *DeLuca v. Allstate N.J. Ins. Co.*, No. 11-4129, 2011 WL 3794229, at *4 (D.N.J. Aug. 25, 2011)). In *Aizen v. American Healthcare Administrative Services*, for example, despite the defendant's company being incorporated in Delaware and headquartered in California, this court determined that New Jersey was the nerve center because New Jersey is where the defendant "directed, controlled, and coordinated both companies' corporate activities." *Id.* at *6. Driving that determination was where the CEO "domina[ted] [the] [defendant's] operations[.]" *Id.* Because the CEO "possesse[d] 'complete operating control' of [the defendant] . . . from his home in New Jersey[.]" the court found that the company's "nerve center" was the CEO's New Jersey home. *Id.* It was of no consequence that most of the defendant's

employees were scattered across the United States rather than in a specific office location, because still, the CEO was directing and controlling the company from New Jersey. *Id.* at *5-6.

Reviewing the jurisdictional facts and sworn statements presented by Defendant in the Gally Declaration, the Court finds that Defendant has come forward with legitimate evidence establishing its “nerve center” is Rockville, Maryland. (*See generally* Gally Decl.) As stated, the Gally Declaration establishes that Otsuka’s major strategic decisions are made from Maryland, not New Jersey. (*Id.*) As stated, this Court may rely on Defendant’s uncontested Declaration submitted in support of its removal papers certifying a company’s location of its major strategic decisionmakers. *Collins v. James W. Turner Constr., Ltd.*, No. 16-2877, 2017 WL 210236, at *4 (D.N.J. Jan. 18, 2017) (relying on a declaration that the company’s nerve center was in Texas, stating that “all major strategic decisions for [defendant] and most major corporate functions, including record-keeping and human resources, were managed out of Texas, not New Jersey.”); *see also Maignan v. Precision Autoworks*, No. 13-3735, 2014 WL 201857, at *3 (D.N.J. Jan. 15, 2014) (finding that plaintiff’s allegations were unable to challenge the sworn statements in defendant’s declaration establishing that defendant’s center of direction, control and coordination was in Pennsylvania, not New Jersey); *Harris v. Bristol-Myers Squibb Co.*, No. 11-6004, 2012 WL 1243260, at *1-2 (D.N.J. Apr. 12, 2012) (finding removal to federal court in New Jersey appropriate where defendant’s general counsel certified, among other things, that the company’s headquarters was in New York, Defendant’s CEO kept his primary office in New York, other members of defendant’s senior leadership kept primary offices in New York, and the board of directors met in New York).

Here, the Gally Declaration certifies that Rockville, Maryland is the center of Otsuka’s direction, control, and coordination, and that Tabah, its CEO, exercises substantial authority over

Defendant's business affairs from the Maryland location. (Gally Decl. ¶¶ 9-10, 14-18 (noting Rabah is empowered "to exercise executive authority over [Defendant's] business affairs and employees" which he does on "nearly a day-to-day basis in Maryland"); *see also id.* ¶ 10 (noting Rabah has "ultimate decision-making authority for corporate decisions in his role [as CEO], and as Chair of the ELT[.]").) Gally further certifies that other high-level officers, including Defendant's Chief Compliance Officer, work out of Maryland. (*Id.* ¶¶ 14-18.) These officers carry out essential company policies, including but not limited to, directing and controlling corporate strategy, corporate records, budgets, compliance, and legal affairs. (*Id.*) Accordingly, the Court finds that Defendant has come forward with sufficient evidence establishing that its principal place of business is Rockville, Maryland. It follows that there is complete diversity of citizenship in this case for the Court to properly exercise subject matter jurisdiction under 28 U.S.C. § 1332. Plaintiff's Motion to Remand is therefore denied.

B. Defendant's Motion to Dismiss

i. Parties' Arguments

The Court turns next to Defendant's Motion to Dismiss the Amended Complaint under Rule 12(b)(6). (*See* Def.'s Mot. Dismiss, ECF No. 20.) Plaintiff's Amended Complaint brings a single claim against Otsuka for alleged retaliation in violation of the CEPA, N.J. Stat. Ann. § 34:19-1, *et seq.* (*See* Am. Compl. ¶¶ 103-29.)

In moving to dismiss, Defendant contends the Amended Complaint does not adequately plead a CEPA claim because Plaintiff "[1] fails to identify a law, rule, regulation, or clear mandate of public policy that she reasonably believed [Defendant] violated[;] [2] "does not allege behavior rising to the level of an adverse employment action under [the] CEPA"; and [3] "neglects to relate a causal connection between whistle-blowing activity and any alleged legally sufficient adverse

employment action.” (*Id.* at 1-2.) At most, Defendant argues, “the [Amended] [C]omplaint shows that [Plaintiff] chose to resign over a disagreement regarding industry best practices and staffing structures rather than illegal conduct, which is not protected under [the] CEPA.” (*Id.* at 2.)

Plaintiff opposes the Motion to Dismiss asserting that, contrary to Otsuka’s position, she engaged in whistleblowing activities starting in the summer of 2022 “when she began making detailed presentations to Otsuka’s [RDLT].” (Pl.’s Opp’n Br. 1-2, ECF No. 26; *see also* Am. Compl. ¶ 9.) Plaintiff voiced concerns that: (1) the number of Otsuka employees under [Plaintiff] and the database lock period were not reasonable pursuant to “industry standards” (Am. Compl. ¶¶ 10-11, 71, 97); (2) Otsuka’s eSource database systems were not up to “industry standards” (*id.* ¶ 77); and (3) Otsuka changed its data to circumvent “hardcoding” guidelines contravening regulatory requirements as defined by the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (“ICH”) (*id.* ¶¶ 58-60).

In her opposition brief, Plaintiff provides additional arguments that Otsuka was violating “specifically identified rules and regulations related to pharmaceutical drug development[,], the FDA[,], and the regulatory agency approval process.” (Pl.’s Opp’n Br. 11.) For example, Plaintiff attaches an FDA article to her opposition brief, titled “New Drug Development and Review Process,” (*See* Cert. of Ayesha Hamilton, Esq., Ex. B, ECF No. 26-3), and refers to several hyperlinks from the FDA’s website concerning “Serious Adverse Events” of patient health and safety that must be reported to the FDA (Pl.’s Opp’n Br. 11-12).⁷ In short, Plaintiff contends that her Amended Complaint sufficiently pleads facts that she was engaged in a CEPA protected whistleblowing activity, that she suffered a covered negative employment action, and that the two are causally linked. (*Id.* at 18.)

⁷ This information is not apparent on the face of the Amended Complaint.

ii. *Analysis*

It is well settled under the CEPA that an employer may not take retaliatory action against an employee who “objects to, or refuses to participate in any activity, policy[,] or practice, which the employee reasonably believes . . . is incompatible with a clear mandate of public policy concerning public health, safety or welfare[.]” N.J. Stat. Ann. § 34:19-3(c)(3). Carrying out this statutory mandate, the New Jersey Supreme Court has prescribed that, to state a claim under CEPA, a plaintiff must adequately allege that:

- (1) he or she reasonably believed that his or her employer’s conduct was violating either a law, rule, or regulation promulgated pursuant to law, or a clear mandate of public policy; (2) he or she performed a “whistle-blowing” activity . . . ; (3) an adverse employment action was taken against him or her; and (4) a causal connection exists between the whistle-blowing activity and the adverse employment action.

Dzwonar v. McDevitt, 828 A.2d 893, 900 (N.J. 2003).

With respect to the first element, a plaintiff must “identify a statute, regulation, rule, or public policy that closely relates to the complained-of conduct.” *Id.* at 901. The New Jersey Supreme Court and the lower courts agree that when a plaintiff fails to provide such law or public policy, the trial court should enter judgment in favor of the defendant. *Safonof v. DirectSat USA*, No. 19-7523, 2020 WL 7074255, at *3 (D.N.J. Dec. 3, 2020) (citing *Dzwonar*, 177 N.J. at 463). “[T]his is an issue of law for the court—[a plaintiff must show] . . . an identifiable ‘law, or a rule or regulation promulgated pursuant to law,’ N.J. Stat. Ann. § 34:19-3(c)(1), or else ‘a clear mandate of public policy concerning the public health, safety or welfare,’ N.J. Stat. Ann. § 34:19-3(c)(3).” *Southward v. Elizabeth Bd. of Educ.*, No. 15-3699, 2017 WL 111924, at *5 (D.N.J. Jan. 11, 2017) (citation omitted). At minimum, a plaintiff is required to identify the law or public policy that she believes was violated. *See Mayorga v. Sonoco Prods. Co.*, No. 12-5067,

2013 WL 1792554, at *5 (D.N.J. Apr. 16, 2013) (dismissing plaintiff's complaint for failure to allege anything that would be a violation of law); *Gaglione v. New Cmty. Corp.*, No. A-06-1015, 2007 WL 2141429, at *2-3 (N.J. Super. Ct. App. Div. Jul. 27, 2007) (stating that a plaintiff's failure to identify any sort of violated statute or regulation, and later claiming on appeal that the defendant may have violated federal tax laws, was not enough to satisfy the first element of a CEPA claim). Indeed, the purportedly unlawful behavior must be more than just a private dispute between the employer and employee. *Mehlman v. Mobil Oil Corp.*, 707 A.2d 1000, 1013 (N.J. 1998); *see also Hitesman v. Bridgeway, Inc.*, 93 A.3d 306, 319-20 (N.J. 2014) (noting that, under *Dzwonar*'s analytical framework, where no such law or policy is forthcoming, a trial court can and should enter judgment in favor of a defendant).

The Court finds that, at this juncture, Plaintiff has not sufficiently alleged "a statute, regulation, rule, or public policy that closely relates to the complained-of conduct" to sustain a claim under the CEPA. *Dzwonar*, 828 A.2d at 901. First, as to Plaintiff's allegations that Otsuka's database lock period was unreasonably short and objectively shorter than industry standard (Am. Compl. ¶¶ 11, 71), this allegation is vague and simply does not identify a statute, regulation, rule, or public policy that Otsuka allegedly violated. Plaintiff's allegations that Otsuka's eSource database systems were "not up to industry standards" (*id.* ¶ 77) are equally vague and disconnected from any identifiable statute, regulation, rule, or policy.

Second, Plaintiff's bare allegations that the data locking protocol would fail to capture "adverse events" that may have "serious consequences in presenting misleading data to [a] regulatory authority such as the FDA" (Am. Compl. ¶ 14) lacks specificity as to what statute or regulation was violated. The Amended Complaint's reference to the FDA generally does not suffice. And while Plaintiff appears to come forward with additional arguments in her opposition

brief as to FDA policies and standards, it is well settled that a plaintiff cannot amend her complaint through an opposition brief. *Pa. ex rel. Zimmerman v. Pepsico*, 836 F.2d 173 (3d Cir. 1988) (“[I]t is axiomatic that the complaint may not be amended by the briefs in opposition to a motion to dismiss.”); *see also Kerrigan v. Otsuka Am. Pharm., Inc.*, No. 12-4346, 2015 WL 5964982, at *3 (E.D. Pa. Oct. 14, 2015) (finding that plaintiff’s conclusory allegation that “FDA regulations” were violated was inadequate to state a claim under the CEPA insofar that the plaintiff did not identify a particular FDA regulation that was violated); *Scioscia v. Walmart Corp.*, No. 23-1940, 2023 WL 8237407, at *2 n.3 (D.N.J. Nov. 28, 2023) (dismissing a CEPA claim and rejecting plaintiff’s attempt to identify a law, or a rule or regulation promulgated pursuant to law, or clear mandate of public policy for the first time in an opposition brief).

As to Otsuka’s staffing levels, Plaintiff again fails to identify any rules, laws, or regulations, requiring proper staffing for a data management team like Plaintiff’s group. (Am. Compl. ¶¶ 84, 94, 97, 104, 114.) In other words, Plaintiff does not come forward with any authority to support that her disagreements over a company’s decision to hire internal employees or retain external contractors is a legitimate whistleblowing activity that could form the basis of a CEPA claim.

Plaintiff’s remaining assertions are conclusory and vague. Plaintiff’s allegations that Defendant altered its data collection program “without informing the sites” which “was a major regulatory issue” (Am. Compl. ¶ 60) are not sufficient because again, Plaintiff has not identified *what* that regulatory issue is. Along the same lines, while Plaintiff contends that she identified that Otsuka was improperly engaged in “hard coding” that violated ICH guidelines (*Id.* ¶¶ 58-59),

Plaintiff does not allege that the ICH guidelines⁸ constitute a statute, regulation, rule, or public policy triggering the CEPA's statutory protections. Thus, as it currently stands, the Court finds that Plaintiff's Amended Complaint fails to allege facts with sufficient specificity to state a claim under the CEPA.⁹

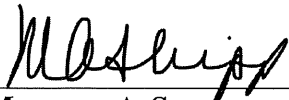
The Court will, however, grant Plaintiff an opportunity to file a Second Amended Complaint and cure the deficiencies mentioned above. Plaintiff has pled facts that, with more specificity, may allege a violation of law or public policy. In making said amendments, Plaintiff should include specific provisions and explanations of the potentially violated statutes, regulations, rules, or public policies. Plaintiff should also describe Otsuka's conduct and allege the ways in which it is substantially related to each listed statute.

⁸ Indeed, Defendant contends that the ICH guidelines are just that—guidelines—and do not constitute a binding rule or regulatory requirement. (Pl.'s Mot. Dismiss 15 n.5.)

⁹ As alternative paths for dismissal, Defendant asserts that: (1) Plaintiff's Amended Complaint fails to establish an adverse employment action and (2) Plaintiff has not shown a causal connection between an alleged whistleblowing activity and any adverse employment action. (*See* Def.'s Mot. Dismiss 18-31.) Because the Court finds that Plaintiff has failed to adequately allege the first element of her CEPA claim, i.e., that she has not identified a law, rule, regulation, or clear mandate of public policy that she believes was violated, the Court dismisses the Complaint on this basis alone and need not reach Defendant's alternative arguments. Plaintiff is, however, encouraged to consider the other necessary elements of her CEPA claim and to ensure that she pleads sufficient facts as to every element of her claim if she chooses to file a Second Amended Complaint.

IV. CONCLUSION

For the reasons stated above, Plaintiff's Motion to Remand is denied, and Defendant's Motion to Dismiss is granted. The Amended Complaint is dismissed without prejudice. Plaintiff is granted leave to file an Amended Complaint. Plaintiff has thirty (30) days to file a Second Amended Complaint, if she so chooses, consistent with this Memorandum Opinion. If Plaintiff fails to file a Second Amended Complaint, the dismissal will be with prejudice. An appropriate Order accompanies this Memorandum Opinion.



MICHAEL A. SHIPPE
UNITED STATES DISTRICT JUDGE